DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 13, 2016

Philips Medical Systems
Theresa Poole
Regulatory Specialist
3000 Minuteman Road
Andover, Massachusetts 01810

Re: K153702
Trade/Device Name: M3290b Philips Intellivue Information Center iX
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DSH, MSX, OUG
Dated: May 4, 2016
Received: May 9, 2016

Dear Theresa Poole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

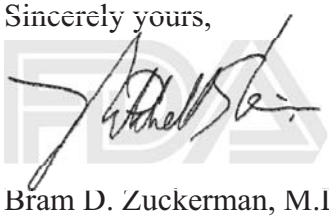
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153702

Device Name
M3290B Philips IntelliVue Information Center iX software Release C.0

Indications for Use *(Describe)*

Intended Use

The intended use of the Information Center Software is to display physiologic waves, parameters, and trends, format data for strip chart recordings and printed reports, and provide the secondary annunciation of alarms from other networked medical devices at a centralized location. The Information Center Software provides for the retrospective review of alarms, physiologic waves and parameters from its database.

An additional intended use of the Information Center Software is to provide primary annunciation of alarms and configuration and control access for networked telemetry monitors.

This product is intended for use in health care facilities by trained healthcare professionals. This product is not intended for home use.

Indications for Use

Indicated for central monitoring of multiple adult and all pediatric subgroups (Newborn (neonate), Infant, Child, Adolescent) patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

Rx Only

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Philips IntelliVue Information Center iX Release C.0

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92(c).

Date Prepared: 4 May 2016

I. Submitter's name and address

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II. Device information

Device Name: M3290B Philips IntelliVue Information Center iX software Revision C.0
Common Name: Central Station
Classification panel: Cardiovascular

Classification names are as follows:

Classification	ProCode	Description
870.1025, II	MHX	Physiological Monitor, Patient Monitor
870.1025, II	DSI	Arrhythmia Detector and Alarm
870.1025, II	MLD	Monitor, ST Alarm
870.2800, II	DSH	Recorder, Magnetic Tape, Medical
870.2300, II	MSX	System, Network and Communication, Physiological Monitors
880.6310, I	OUG	Medical Device Data System

III. Predicate device information

Trade name: M3290B Philips IntelliVue Information Center iX software Revision B.01
Manufacturer: Philips Medical Systems
510(k) clearance: K143057

510(k) Summary

Classification name	Central Station
Device class:	Class II
Classification regulation:	21 CFR 892.2300
Classification panel:	Cardiovascular
Product code:	MSX

IV.Device Description

The Philips IntelliVue Information Center iX Software Revision C.0 is central station software that runs on off-the-shelf Windows PCs and servers which can connect to recorders for waveform printing. It displays physiologic waves and parameters from multiple patient connected monitors and telemetry devices in summary or detailed format, and generates alarm signals. It provides retrospective review applications and a variety of data import and export functions.

V. Intended use/ Indications for Use

Intended Use

M3290B Intended Use

Intended Use Statement, as described in its labeling, has not changed from that of the predicate device.

The intended use of the Information Center Software is to display physiologic waves, parameters, and trends, format data for strip chart recordings and printed reports, and provide the secondary annunciation of alarms from other networked medical devices at a centralized location. The Information Center Software provides for the retrospective review of alarms, physiologic waves and parameters from its database.

An additional intended use of the Information Center Software is to provide primary annunciation of alarms and configuration and control access for networked telemetry monitors.

This product is intended for use in health care facilities by trained healthcare professionals. This product is not intended for home use.

Rx Only

Indications for Use

M3290B Indications for Use

The indications for use of the device, as described in its labeling, have not changed from that of the predicate device.

Indicated for central monitoring of multiple adult and all pediatric subgroups (Newborn (neonate), Infant, Child, Adolescent) patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

VI.Comparison of Technological Characteristics with the Predicate Device

The device has the same technological characteristics as the legally marketed predicate devices. This software change include items listed in the table below.

Comparative Characteristic	**Predicate: M3290B IntelliVue Information Center Software Release B.01 (K143057)**	**Proposed Device: M3290B Philips IntelliVue Information Center iX Software Release C.0**
Data Acquisition Services	IntelliVue family of patient montiors	Added Efficia Release C.0 allows data from the Philips Efficia monitors to be received, stored, exported and managed.
Outbound Data Services	Web/Mobility PDX	Web/Mobility Release C.0 allows for transmission of a web interface to the IntelliVue bedside monitors to be opened in a window where the bedside monitor has the capability to use this feature. PDX – Data Warehouse Release C.0 expanded the ability to store data sets from various additional sources and the storage of complex data.
Applications	Surveillance Display Set Up Alarm Measurement & Device Control	Surveillance Release C.0 added to the already presented information for the Early Warning Score (EWS) sent from the IntelliVue bedside monitor. Display Setup Release C.0 added the ability, when configured, to auto assign a bed label to a

Comparative Characteristic	Predicate: M3290B IntelliVue Information Center Software Release B.01 (K143057)	Proposed Device: M3290B Philips IntelliVue Information Center iX Software Release C.0
		sector to support the limited configuration option for Philips Efficia monitors. Alarm Measurement and Device Control Release C.0 added the ability to display the integration of the Philips Efficia monitor in a way similar to the IntelliVue monitor.
Domain Specific Services	Patient & Equipment Management ST/AR	Patient and Equipment Management Release C.0 adds to equipment management the management association, to aid in the management of 'orphan beds'. ST/AR Release C.0 allows data previously gathered by the algorithm to be displayed. No changes to the algorithm are present.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Summary of Non-clinical testing

No performance standards have been issued under the authority of Section 514. The M3290B Philips IntelliVue Information Center iX software Release C.0 was tested in accordance with Philips verification and validation processes. Quality Assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validations

Summary of Clinical Testing

Clinical Performance testing for M3290B Philips IntelliVue Information Center iX software Release C.0 was not performed, as there were no new clinical applications that had hazards or risk mitigations that required a clinical performance testing to support equivalence.

Conclusions drawn from the Non-clinical and Clinical testing

Verification, validation, and testing activities, where required to establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate are performed. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The M3290B Philips IntelliVue Information Center iX software Release C.0 meets all defined reliability requirements and performance claims.

VIII. Conclusion

M3290B Philips IntelliVue Information Center iX software Release C.0 is substantially equivalent to the predicate device M3290B Philips IntelliVue Information Center iX software Release B.01 (K143057) in terms of design features, fundamental scientific technology, intended use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance testing, which complied with the requirements specified in the international and FDA-recognized consensus standards. The non-clinical performance tests provided in this 510(k) premarket notification demonstrate that the subject device is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.